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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/665,455

09/18/2003

Arlene A. Wise

S-100,654

6835

35068

7590

07/03/2006

LOS ALAMOS NATIONAL SECURITY, LLC
LOS ALAMOS NATIONAL LABORATORY
PPO. BOX 1663, LC/IP, MS A187
LOS ALAMOS, NM 87545

EXAMINER

RAMIREZ, DELIA M

ART UNIT

PAPER NUMBER

1652

DATE MAILED: 07/03/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/665,455

Applicant(s)

WISE ET AL.

Examiner

Delia M. Ramirez

Art Unit

1652

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 April 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 9-25 is/are pending in the application.
- 4a) Of the above claim(s) 22-24 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 9-21 and 25 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☒ Other: alignments

DETAILED ACTION

Status of the Application

Claims 9-25 are pending.

Applicant's election with traverse of Group I, claims 9-21 and 25 drawn to a method of detecting 2-chlorophenol, 2,4-dichlorophenol, 2,4-dimethylphenol, 4-nitrophenol, phenol, and 2-nitrophenol, in a communication filed on 4/14/2006 is acknowledged.

Applicant's traverse is on the ground(s) that the polynucleotides of Groups II-VIII are related as they encode mutants of the same protein. Applicant also submits that the mutations are limited to a certain domain of the protein and that use of the nucleic acids as probes of different targets is unlikely. Applicant notes that the specification indicates that some of these mutations are silent and do not alter the encoded amino acid. Applicant argues that there is a shared common utility among all the nucleic acids as encoding mutants of the same protein, wherein said mutants are effectors molecules capable of being used to drive the expression of a reporter gene following recognition of a phenolic compound. Applicant submits that there is a shared structural feature essential to that activity as each mutant contains an effector domain which triggers the expression of a reporter gene. Applicant refers to MPEP 803.02 to indicate that the claimed nucleic acids meet the standards of a proper Markush group. Finally, Applicant submits that the number of species in the Markush group is sufficiently small to allow search of all of them without imposing an undue burden of search on the Office.

Applicant's arguments have been fully considered but are not deemed persuasive to withdraw the restriction requirement. While it is agreed that the nucleic acids of Groups II-VIII have been disclosed as encoding mutants of the same protein, there is no indication that these mutants are obvious variations of each other. In fact, the specification discloses that some of these variants will detect some phenolic compounds but not others. Thus, while the nucleic acids of Groups II-VIII share the generic function of encoding an effector molecule capable of driving the expression of a reporter gene in the presence of a

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phenolic compound, each of these nucleic acids encode a protein having a different effector activity by virtue of “sensing” a different phenolic compound. Contrary to Applicant’s assertion, there is no shared utility as the nucleic acids would be used to detect different phenolic compounds. With regard to arguments that the nucleic acids of Groups II-VIII share a very similar structure and that some of the nucleic acids contain silent mutations not affecting the encoded amino acid, it is noted that upon an alignment of the polypeptides encoded by the polynucleotides of SEQ ID NO: 1-7, it has been found that there are 11 mismatches among all these polypeptides at positions 4, 10, 42, 58, 61, 112, 116-117, 141, 146 and 163 (all polypeptides are 180 amino acids long). There is no one polypeptide species which is identical to another, which would be the case if the mutations in the nucleic acids were to be silent. See attached alignments. Thus, while it is agreed that in general the sensor domain is a structural feature required to detect phenolic compounds, there is no shared substantial feature disclosed as being essential to detect each of the different phenolic compounds associated with the mutants encoded by the nucleic acids of Groups II-VIII. As stated in M.P.E.P. § 803.04, “Nucleotide sequences encoding different proteins are structurally distinct chemical compounds and are unrelated to one another”. Therefore, for the reasons stated above, the polynucleotides of SEQ ID NO: 1-7 are patentably distinct inventions and are not considered elements of a Markush-type group.

With regard to arguments that the members of the alleged Markush group are sufficiently few in number and closely related that a search and examination of all of the groups can be made without serious burden, it is noted that a search of all the nucleic acids listed would impose an undue burden on the Office, as each one of the inventions would require a separate patent/non-patent literature search, as well as a sequence search. These searches are not co-extensive. In addition, while performing a search, different keywords would be required. Thus, a search of Groups II-VIII in a single application would impose an undue burden on the Office

The requirement as it relates to Groups II-VIII is deemed proper and therefore is made FINAL.

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Claims 22-24 are withdrawn from further consideration by the Examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Applicant is advised that upon aligning the sequences of the specification, it was found that the polynucleotide of SEQ ID NO: 1 does not encode the polypeptide of SEQ ID NO: 8. It is noted that the protein alignments provided with this Office action were not performed with SEQ ID NO: 8-13 but rather with the protein translations of the polynucleotides of SEQ ID NO: 1-7 due to the discrepancy found. A protein translation of SEQ ID NO: 1 shows a glutamic acid residue at position 4 whereas SEQ ID NO: 8 shows a lysine residue. Applicant is requested to carefully review the sequence listing (paper and electronic form) and correct any additional discrepancies overlooked by the Examiner.

Supplemental Restriction Requirement

1. The instant Office Action is a supplemental restriction requirement of claims 9-21 and 25. This supplemental requirement is at the discretion of the examiner (see MPEP 802 and 37 CFR 1.142) and is deemed appropriate and necessary in view of the plurality of claimed patentably distinct inventions.

2. Restriction of claims 9-21 and 25 to one of the following inventions is required under 35 U.S.C. 121:

- Ia. Claims 9-12, 21 and 25, drawn in part to a method of detecting a phenolic compound with a mutant labeled DmpR-B21 (SEQ ID NO: 3), classified in class 435, subclass 29.
- Ib. Claims 9-10, 21 and 25, drawn in part to a method of detecting a phenolic compound with a mutant labeled DmpR-B23 (SEQ ID NO: 4), classified in class 435, subclass 29.
- Ic. Claims 9-10, 15-16, 21 and 25, drawn in part to a method of detecting a phenolic compound with a mutant labeled DmpR-D9 (SEQ ID NO: 6), classified in class 435, subclass 29.

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- Id. Claims 11-12, 21 and 25, drawn in part to a method of detecting a phenolic compound with a mutant labeled DmpR-B17#2 (SEQ ID NO: 2), classified in class 435, subclass 29.
- Ie. Claims 11-12, 19-20, 21 and 25, drawn in part to a method of detecting a phenolic compound with a mutant labeled DmpR-B9 (SEQ ID NO: 1), classified in class 435, subclass 29.
- If. Claims 11-12, 21 and 25, drawn in part to a method of detecting a phenolic compound with a mutant labeled DmpR-D12 (SEQ ID NO: 7), classified in class 435, subclass 29.
- Ig. Claims 13-14, 17-18, 21 and 25, drawn in part to a method of detecting a phenolic compound with a mutant labeled DmpR-B31 (SEQ ID NO: 5), classified in class 435, subclass 29.

The inventions are distinct, each from the other because of the following reasons:

3. Inventions Ia-Ig are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, while the methods of inventions Ia-Ig are methods of detection of phenolic compounds, each of the methods use different products (mutants of SEQ ID NO: 1-7), and/or detect different phenolic compounds, thus producing different results. See extensive discussion above with regard to the distinctness of the mutants of SEQ ID NO: 1-7.

4. As set forth in MPEP § 803, the criteria for a proper restriction between patentably distinct inventions requires that the inventions must be independent or distinct as claimed, and a search of all the inventions would impose a serious burden on the examiner. Groups I-VIII have been shown to be independent or distinct, for the reasons set forth above. MPEP § 803 also indicates that a serious burden on the examiner may be prima facie shown if the Examiner shows by appropriate explanation either separate classification, separate status in the art, or a different field of search. A search of the inventions

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of Groups Ia-Ig would require at a separate patented/non-patented literature search, class/subclass search, and sequence search. These searches are not co-extensive. Therefore a comprehensive examination of all groups would impose an undue burden on the Examiner. Thus, restriction for examination purposes as indicated is proper.

5. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement can be traversed (37 CFR 1.143).

6. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

7. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Delia M. Ramirez whose telephone number is (571) 272-0938. The examiner can normally be reached on Monday-Friday from 8:30 AM to 5:00 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Ponnathapura Achutamurthy can be reached on (571) 272-0928. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571) 272-1600.



Delia M. Ramirez, Ph.D.
Patent Examiner
Art Unit 1652

DR
June 18, 2006


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Db 121 CAGTTTCAGCGATGCGCACTTTCCGCGGAAATGCTCAATACCTTGGGCATCGAACGC 180
Qy 181 GCCAAGGGCTGTGTTCTGCGSCCATGTTACCACTCCGAGCTGAAGATGCCAATGAGCC 240
Db 181 GCCAAGGGCTGTGTTCTGCGSCCATGTTACCACTCCGAGCTGAAGATGCCAATGAGCC 240
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Db 241 AGGAAGCTGAGACCGAATGCGACGAAATGCGCAATGTTCTGCTGGGCGGCAATGAT 300
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Qy 481 TCGGCGTTTCAATGAGGCGCGGAAATCATCTTCAAGAAATGACGTCGCGCGGCTGCGCG 540
Db 481 TCGGCGTTTCAATGAGGCGCGGAAATCATCTTCAAGAAATGACGTCGCGCGGCTGCGCG 540

RESULT 3
US-10-665-455-4
; Sequence 4, Application US/10665455
; GENERAL INFORMATION:
; APPLICANT: The Regents of the University of California
; APPLICANT: Wise, Arlene
; TITLE OF INVENTION: Detection Of Phenols Using Engineered Bacteria
; FILE REFERENCE: S-91, 714
; CURRENT APPLICATION NUMBER: US/10/665,455
; CURRENT FILING DATE: 2003-09-18
; PRIOR APPLICATION NUMBER: US/09/520,538
; PRIOR FILING DATE: 2000-03-08
; NUMBER OF SEQ ID NOS: 17
; SOFTWARE: PatentIn version 3.0
; SEQ ID NO 4
; LENGTH: 540
; TYPE: DNA
; ORGANISM: Pseudomonas sp. CF600
US-10-665-455-4

Query Match 98.8%; Score 533.6; DB 1; Length 540;
Best Local Similarity 99.3%; Pred. No. 0.21;
Matches 536; Conservative 0; Mismatches 4; Indels 0; Gaps 0;

Qy 1 ATGCCGATGAGTACAGGCTGAATGCAGACATCCGATTTCAGAGACCTGACCAACTG 60
Db 1 ATGCCGATGAGTACAGGCTGAATGCAGACATCCGATTTCAGAGACCTGACCAACTG 60
Qy 61 ATCCACTTCAGAGATGGAAGGCAAGATCTGCTTGGCGAACAAGCGCATGCTGTGCTG 120
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Qy 421 CTGGGGCAGATGCAAGACCCGCTGTGCTGAGCTGTGCTGCTACGCTGCGCTTATTC 480
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Qy 481 TCGGCGTTTCAATGAGGCGCGGAAATCATCTTCAAGAAATGACGTCGCGCGGCTGCGCG 540
Db 481 TCGGCGTTTCAATGAGGCGCGGAAATCATCTTCAAGAAATGACGTCGCGCGGCTGCGCG 540

RESULT 4
US-10-665-455-7
; Sequence 7, Application US/10665455
; GENERAL INFORMATION:
; APPLICANT: The Regents of the University of California
; APPLICANT: Wise, Arlene
; TITLE OF INVENTION: Detection Of Phenols Using Engineered Bacteria
; FILE REFERENCE: S-91, 714
; CURRENT APPLICATION NUMBER: US/10/665,455
; CURRENT FILING DATE: 2003-09-18
; PRIOR APPLICATION NUMBER: US/09/520,538
; PRIOR FILING DATE: 2000-03-08
; NUMBER OF SEQ ID NOS: 17
; SOFTWARE: PatentIn version 3.0
; SEQ ID NO 7
; LENGTH: 540
; TYPE: DNA
; ORGANISM: Pseudomonas sp. CF600
US-10-665-455-7

Query Match 98.8%; Score 533.6; DB 1; Length 540;
Best Local Similarity 99.3%; Pred. No. 0.21;
Matches 536; Conservative 0; Mismatches 4; Indels 0; Gaps 0;

Qy 1 ATGCCGATGAGTACAGGCTGAATGCAGACATCCGATTTCAGAGACCTGACCAACTG 60
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Db 241 AGGAAGCTGAGACCGAATGCGACGAAATGCGCAATGTTCTGCTGGGCGGCAATGAT 300
Qy 301 TCACCTAAGGCTGTGTCAGAGTCCGCCCCACGAGTGCATATTCACAAAGAAATACGGG 360
Db 301 TCACCTAAGGCTGTGTCAGAGTCCGCCCCACGAGTGCATATTCACAAAGAAATACGGG 360
Qy 361 CGCTTCTATGCGCAGATGAGTGAATGCACTGTTGCAAGGTGAAATCTCCACAGCCGAC 420
Db 361 CGCTTCTATGCGCAGATGAGTGAATGCACTGTTGCAAGGTGAAATCTCCACAGCCGAC 420
Qy 421 CTGGGGCAGATGCAAGACCCGCTGTGCTGAGCTGTGCTGCTACGCTGCGCTTATTC 480
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DB 481 TCGGCGTTCAATGCGCCGCGGAATCATCTTCAAGAGATGAGCTCCGCGGCTGGCGGCGC 540

RESULT 5
US-10-665-455-5
Sequence 5, Application US/10665455
GENERAL INFORMATION:
APPLICANT: The Regents of the University of California
TITLE OF INVENTION: Detection Of Phenols Using Engineered Bacteria
FILE REFERENCE: S-91,714
CURRENT APPLICATION NUMBER: US/10/665,455
CURRENT FILING DATE: 2003-09-18
PRIOR APPLICATION NUMBER: US/09/520,538
PRIOR FILING DATE: 2000-03-08
NUMBER OF SEQ ID NOS: 17
SOFTWARE: PatentIn version 3.0
SEQ ID NO 5
LENGTH: 540
TYPE: DNA
ORGANISM: Pseudomonas sp. CF600
US-10-665-455-5

Query Match Best Local Similarity 98.2%; Score 530.4; DB 1; Length 540;
Matches 534; Conservative 0; Mismatches 6; Indels 0; Gaps 0;

QY 1 ATCCGATCGAGTACAGCCTGAAATCCAGCACTCCGATTTCAGAGACTGACCAACTG 60
DB 1 ATCCGATCGAGTACAGCCTGAAATCCAGCACTCCGATTTCAGAGACTGACCAACTG 60
QY 61 ATCCACTTCAGAGATGAGAGCAAGATCTGCTTGGCGAACAAGCATGCTGTTGCTG 120
DB 61 ATCCACTTCAGAGATGAGAGCAAGATCTGCTTGGCGAACAAGCATGCTGTTGCTG 120
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DB 121 CAGTTTCAAGCATGAGCCAGCTTCCGCGGGAATGTCATACCTCGGCGCATCGAACG 180
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DB 361 CGCTTCTATGCCAGATGAGATGAGATCGATCGTTCGAGGTGGAATTCGCCAGACGAC 420
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DB 481 TCGGCGTTCAATGCGCCGCGGAATCATCTTCAAGAGATGAGCTCCGCGGCTGGCGGCGC 540

RESULT 6
US-10-665-455-6
Sequence 6, Application US/10665455
GENERAL INFORMATION:
APPLICANT: The Regents of the University of California
TITLE OF INVENTION: Detection Of Phenols Using Engineered Bacteria
FILE REFERENCE: S-91,714
CURRENT APPLICATION NUMBER: US/10/665,455

QY 1 ATCCGATCGAGTACAGCCTGAAATCCAGCACTCCGATTTCAGAGACTGACCAACTG 60
DB 1 ATCCGATCGAGTACAGCCTGAAATCCAGCACTCCGATTTCAGAGACTGACCAACTG 60
QY 61 ATCCACTTCAGAGATGAGAGCAAGATCTGCTTGGCGAACAAGCATGCTGTTGCTG 120
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QY 481 TCGGCGTTCAATGCGCCGCGGAATCATCTTCAAGAGATGAGCTCCGCGGCTGGCGGCGC 540
DB 481 TCGGCGTTCAATGCGCCGCGGAATCATCTTCAAGAGATGAGCTCCGCGGCTGGCGGCGC 540

Query Match Best Local Similarity 98.2%; Score 530.4; DB 1; Length 540;
Matches 534; Conservative 0; Mismatches 6; Indels 0; Gaps 0;

Search completed: April 25, 2006, 09:26:47
Job time : 2 secs